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- 2. In an Office Action dated October 9, 2002, the Examiner rejected the pending claims as allegedly anticipated by U.S. Patent No. 5,290,544 ("Shimono").
- On February 10, 2003, applicants submitted an Amendment in Response to the October 9, 2002 Office Action. In the Amendment applicants (1) amended the claims (without prejudice) to include a proviso that the bioactive glass does not comprise ions of silver, copper or zinc; and (2) pointed out that Shimono was not relevant to the pending claims.
- 4. In a Final Office Action dated May 20, 2003, the Examiner withdrew the anticipation rejection but rejected the pending independent claims as allegedly obvious over Shimono.
- On November 19, 2003, applicants filed a Communication in Response to the May 20, 2003 Office Action and again pointed out that Shimono was not relevant to the pending claims.
- 6. In an Advisory Action mailed March 15, 2004, the Examiner stated that applicants' previous submission had not placed the claims in condition for allowance (thereby maintaining the rejection based on Shimono).
- 7. Applicants filed an RCE on April 15, 2004.
- 8. On June 3, 2004, applicants' undersigned representative and the Examiner, along with the Examiner's supervisor, conducted an in-person interview at the USPTO to discuss the relevancy of Shimono to the pending claims. During the interview, it was agreed by all present that Shimono was indeed not relevant to the pending claims. (At that point the application had already been pending for more than three years.)

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- 9. In an Office Action dated September 10, 2004, the Examiner rejected the pending independent claims as allegedly anticipated by U.S. Patent No. 6,517,863 ("LaTorre").
- 10. On March 7, 2004, applicants filed a Communication explaining why LaTorre did not anticipate (or render obvious) the pending independent claims.
- 11. In a Final Office Action dated June 3, 2005, the Examiner withdrew the anticipation rejection, but rejected the independent claims as allegedly obvious over LaTorre.
- 12. On August 16, 2005, applicants filed a Communication pointing out two fundamental errors committed by the Examiner in rejecting the independent claims as obvious over LaTorre. Those errors included (1) failure to apply the obviousness analysis to the pending claims, coupled with an improper emphasis on isolated disclosures in applicants' specification; and (2) failure to consider each of the unexpected and surprising results achieved by the claimed invention. Those unexpected and surprising results were discussed in detail.
- 13. In an Advisory Action dated September 9, 2005, the Examiner stated that the August 16, 2005 Communication had not placed the application in condition for allowance (thereby maintaining the rejection based on LaTorre). The Advisory Action will be discussed in more detail below.
- 14. Today, December 2, 2005, applicants are concurrently filing a 2nd RCE.

The September 9, 2005 Advisory Action

In the Advisory Action the Examiner stated that applicants' arguments in the August 16, 2005 Communication were not persuasive since LaTorre allegedly teaches that the use of

aqueous or hydrophilic components <u>are optional and not critical</u>. Similarly, the Examiner alleged that the use of additional antimicrobials is considered <u>optional</u> by LaTorre.

In response, applicants first point out the significant difference between the subject matter of the LaTorre invention and the subject matter of applicants' presently claimed invention. LaTorre is directed to compositions and methods for <u>hardening and strengthening nails</u>. In sharp contrast, the presently claimed invention is directed to long-lasting <u>cosmetic preservative compositions</u> comprising bioactive glass and a <u>substantially anhydrous</u> cosmetic formulation (and methods of making same).

It is important to understand that while LaTorre may use the word "optional" to describe certain compositions, a careful examination of the reference shows that all of the <u>functional</u> compositions described therein <u>require</u> an aqueous base and are not long-lasting. In other words, in order for LaTorre's compositions to work it is not optional, but rather critical, to use aqueous based formulations. LaTorre's use of the term "optional" clearly does not teach or suggest that the compositions intended to strengthen and harden nails could also work as substantially anhydrous, long-lasting cosmetic preservatives.

In addition, while LaTorre also may use the word "optional" with respect to the addition of antimicrobial agents, LaTorre does not teach or suggest any composition that would provide long-lasting anti-microbial activity in a cosmetic formulation, much less a substantially anhydrous cosmetic formulation. As stated above, LaTorre is directed to compositions for strengthening and hardening nails. The "optional" nature of antimicrobials in that type of formulation is not at all relevant to the long-lasting preservative effects obtained by applicants' presently claimed invention.

Applicants maintain that each of the above-stated distinctions is, by itself, sufficient to overcome the rejection based on LaTorre. Accordingly, applicants again respectfully request that the Examiner reconsider and withdraw the rejection.

* * * * *

For the sake of completeness applicants will once again set forth below, in greater detail, the primary distinctions between LaTorre and the present invention.

Applicants again point out that LaTorre does not disclose, teach or suggest the cosmetic compositions or methods of making cosmetic compositions which (1) provide a long duration of effectiveness; (2) are substantially anhydrous; and (3) do not require the presence of additional anti-microbial agents. In contrast, LaTorre is directed to compositions for strengthening and hardening nails.

Long Duration Of Effectiveness

LaTorre does not disclose <u>stable</u> cosmetic compositions (or methods of making such compositions) comprising bioactive glass and a substantially anhydrous cosmetic formulation.

Rather, LaTorre discloses that:

It is preferable that the glass not be significantly prereacted prior to application to the nails. This can be achieved, for example, by mixing the bioactive glass and water to form the compositions and applying the composition to the nails immediately after mixing. [Emphasis supplied.] [Col. 5, lines 52-56.]

In contrast, the presently claimed invention provides stable, long-lasting compositions (and methods of making same) comprising bioactive glass and a substantially anhydrous cosmetic formulation. Such compositions have an extended duration of effect and, unlike LaTorre's nail hardening compositions, do not need to be used immediately upon combination.

Substantially Anhydrous

As specifically recited in independent claims 135 and 153, the presently pending claims require the presence of a substantially anhydrous cosmetic formulation. Since LaTorre does not disclose, teach or suggest a cosmetic composition comprising a substantially anhydrous cosmetic formulation, LaTorre cannot render obvious the presently pending claims.

More particularly, and as stated previously, LaTorre stresses the criticality of using aqueous solutions or hydrophilic ("water-loving") polymers for the LaTorre nail hardening compositions to work. For instance, LaTorre discloses using either an aqueous solution or, alternatively, a gel based formulation (which uses a hydrophilic polymer) to create a layer of hydroxyapatite or other calcium phosphate mineral on the nail. (Col. 2, lines 48-61.) LaTorre further states that "[a]n effective nail-enhancing amount of bioactive glass is defined as an amount capable of providing the nail surface with at least a thin coating of hydroxyapatite." (Col. 3, lines 30-33.) LaTorre also states that the theory behind the invention is the "adsorption of hydronium ions from a solution and a release of sodium and/or calcium ions..." (Emphasis supplied.) (Col. 3, lines 38-40.) Thus, aqueous solutions and hydrophilic polymer solutions are critical to LaTorre.

Importantly, LaTorre discloses beyond doubt the criticality (for the LaTorre invention) of aqueous or hydrophilic-based compositions when describing formulations which include bioactive glass. In doing so LaTorre states.

The bioactive glass or extract of bioactive glass <u>may be</u> <u>administered to the nail in a topical formulation</u>, such as in the form of a suspension, lotion, cream (water-in-oil emulsion) or gel, <u>provided that the formulation includes a sufficient amount of water</u> such that the ions can be formed and allowed to react with the nail to form the hydroxyapatite layer. [Emphasis supplied.] [Col. 4, line 62 - Col. 5, line 3.]

Example 1 in LaTorre (the only example in which an arguably cosmetic formulation comprising bioactive glass is described), used an equal volume of bioactive glass and <u>water</u> to form a paste. (See Col. 6, lines 45-62.)

Does Not Require The Presence Of Additional Anti-Microbial Agents

LaTorre also concedes the need for additional anti-microbial additives to provide a significant anti-microbial effect even in the context of nail hardening and strengthening compositions intended for immediate use. In contrast, the presently claimed invention provides significant and long-lasting anti-microbial effects without the use of anti-microbial additives.

This is a significant unexpected and surprising result that, *inter alia*, saves both the cost of anti-microbial additives and the time that would be required for incorporating anti-microbials into a cosmetic formulation.

Dependent Claims

Applicants maintain that claims 139-152 and 157-170 are not rendered obvious by LaTorre in view of Vatter. In the Advisory Action, the Examiner only relies on Vatter for the proposition that it was known in the cosmetic art to employ cosmetic additives. There is no disagreement between the Examiner and applicants' representative that that Vatter fails to cure the deficiencies of LaTorre discussed above.

Conclusion

In view of the foregoing, applicants respectfully request that the Examiner reconsider and withdraw the rejections set forth in the June 3, 2005 Final Office Action (which were restated in the September 9, 2005 Advisory Action) and allow the presently pending claims.

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No fee is believed to be necessary in connection with the filing of this Reply. If any fee is deemed to be necessary, applicants hereby authorize such fee to be charged to Deposit Account No. 50-0540.

If a telephone interview would be of assistance in advancing the prosecution of this application, applicants' undersigned attorney encourages the Examiner to telephone him at the number provided below.

Respectfully submitted,

Dated: December 1, 2005

Robert E. Alderson, Reg. No. 44,500

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